K052355

SEP 14 2005

2.2 510(k) Summary

510(k) Summary for Special 510(k) Notification
U-Systems Diagnostic Ultrasound System

Prepared July 29, 2005

Product Name: Modified FFBU Diagnostic Ultrasound System
[ABUS Diagnostic Ultrasound System]

Manufacturer: U-Systems Inc.
110 Rose Orchard Way
San Jose, CA 95134
Telephone (408) 750-1323
Fax (408) 571-8979

Generic Name: Diagnostic Ultrasound System

Classification Name: Ultrasound Imaging System and Transducers (Class II); Classification codes:
IYO 892.1560 System, Imaging Pulsed Echo, Ultrasonic
ITX 892.1570 Transducer, Ultrasonic, Diagnostic

Contact Person: Robert F. Lawrence.
110 Rose Orchard Way
San Jose, California 95134
Telephone 408 750 1323
e-mail: blawrnece@u-sys.com

A. Legally Marketed Predicate Device

The ABUS System modification is substantially equivalent to the sponsor's original FFBU device (K032640) as well as Siemens Antares DUS (K023720) and the ContextVision Sharp Image View (K024028). The intended use and the technological characteristics of the modification are the same as the predicate devices.

B. Device Description

The ABUS system, with automated ultrasound im-aging of the breast, gives the radiologist a cost effective solution for reviewing the ultrasound images with the corresponding mammogram.

The FFBU Diagnostic Ultrasound System modification represents limited hardware and software changes to the Sponsor's predicate device.

C. Intended Use

The device is indicated for use as an adjunct to mammography for B-mode ultrasonic imaging of a patient's breast when used with an automatic scanning linear array transducer.

D. Substantial Equivalence

The ABUS System modification is substantially equivalent to the original FFBU device (K032640) as well as Siemens Antares DUS (K023720) and the ContextVision Sharp Image View (K024028).

E. PERFORMANCE DATA

The ABUS System performance has been verified according to the U-Systems process for Design Control which is compliant with 21 CFR Part 820.30.

2.3 510(k) Diagnostic Ultrasound Indications for Use Form

The ultrasound intended use categories are identical to the "small parts" indication cleared for the FFBU Diagnostic Ultrasound System. The modified FFBU System has B-mode as well as Harmonic Imaging, and Spatial Compounding capability and is available with three linear array transducers. A Speckle Reduction feature has been added to the software. The following ultrasound indication for use forms show the probe previously cleared for the original system as well as forms for the new modes and new transducers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 14 2005

U-Systems, Inc.
% Mr. Tamas Borsai
Responsible Third Party Official
TUV Rheinland of North America
1279 Quarry Lane, Suite A
PLEASANTON CA 94566

Re: K052355
Trade Name: Automated Breast Ultrasound System, (Model ABUS)
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: IYO and ITX
Dated: August 25, 2005
Received: August 29, 2005

Dear Mr. Borsai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Automated Breast Ultrasound System, (Model ABUS), as described in your premarket notification:

Transducer Model Number

L9-5XW
L10-5XW
L12-6XW

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): K052355

Device Name: Automated Breast Ultrasound System. Model ABUS

General Indication for Use
An ultrasonic pulsed echo imaging system is intended to project a pulsed sound beam into body tissue to determine the depth or location of the tissue interfaces and to measure the duration of an acoustic pulse from the transmitter to the tissue interface and back to the receiver. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

Specific Indications For Use
The device is indicated for use as an adjunct to mammography for B-mode ultrasonic imaging of a patient's breast when used with an automatic scanning linear array transducer.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052355

Diagnostic Ultrasound Indications for Use Forms (No New Indications for Use; Previously Cleared Indications for Use)

Diagnostic Ultrasound Indications for Use

510(k) Number(s):

Device Name: Automated Breast Ultrasound System, Model ABUS

Intended Use: Diagnostic ultrasound imaging of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)*	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (breast, thyroid, testes)		P								N Note 1&2
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Laproscopic										
Peripheral Vascular										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										

Note 1: Harmonic Imaging
Note 2: Spatial Compounding

The USI FFBU System is intended for breast examinations.

N = new indication
P = previously cleared by FDA

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052355

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

Diagnostic Ultrasound Indications for Use

510(k) Number:

Device Name: L9-5XW MHz Transducer
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)*	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (breast, thyroid, testes)		P								N Note 1&2
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Laproscopic										
Peripheral Vascular										
Musculo-skeletal Conventional										
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510(k) Number K052355

Prescription Use ✓

Diagnostic Ultrasound Indications for Use

510(k) Number:

Device Name: L10-5XW MHz Transducer
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)*	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (breast, thyroid, testes)		N								N Note 1&2
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
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Laproscopic										
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Musculo-skeletal Conventional										
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Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052355

Prescription Use ✓

Diagnostic Ultrasound Indications for Use

510(k) Number:

Device Name: L12-6XW MHz Transducer
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)*	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (breast, thyroid, testes)		N								N Note 1&2
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
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Intravascular										
Laproscopic										
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Musculo-skeletal Conventional										
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Prescription Use √